September 1967— August 1968	USPHS Traineeship in Neurological and SensoryDisease (Mental Retardation), Children's Diagnostic and Development Center, Georgetown University Hospital, Washington, D.C.

MEDICAL LICENSURE:

Pennsylvania—August 1961
District of Columbia—April 1968
Virginia—June 1971
Maine—July 1975

BOARD CERTIFICATION:

Diplomate American Board of Pediatrics—May 1965
Recertified June 1983

MILITARY SERVICE:

Captain, United States Air Force (Medical Corps);
Base Pediatrician, Davis Monthan AFB,
Tucson, Arizona,
July 1963—June 1965

APPOINTMENTS:

Chief of Medical Unit (Peru), The People-to-People Health Foundation, Incorporated (Project HOPE). Trujillo, Peru, August 1965—July 1967

Visiting Professor of Pediatrics, National University of Trujillo. Peru, August 1965—July 1967

Attending Pediatrician, Children's Hospital National Medical Center, September 1968—December 1975

Assistant Professor of Pediatrics, George Washington University School of Medicine, September 1968—July 1971

Associate Director, Program for Learning Studies, Children's Hospital National Medical Center, September 1970—September 1974

Associate Professor of Child Health and Development, George Washington University School of Medicine, July 1971—July 1977

Visiting Professor and Consultant in Ambulatory Pediatrics, University of Arizona College of Medicine, March & April, 1974

Associate Director, Pediatric Training Program, Children's Hospital National Medical Center, October 1974—July 1977

Senior Attending Pediatrician and Vice Chairman, Department of General Medicine, Children's Hospital National Medical Center, January 1976—July 1977

Adjunct Associate Professor of Child Health and Development, George Washington University School of Medicine, July 1977—June 1980

Consultant Pediatrician, The People-to-People Health Foundation, Incorporated (Project HOPE), Trujillo, Peru, July 1977—January 1978

Attending Pediatrician, Kennebec Valley Medical Center, Augusta, Maine, January 1978—to present

Pediatrician, Winthrop Area Medical Center, Winthrop, Maine, January 1978—July 1984

Pediatrician, Winthrop Family Pediatrics Center, Winthrop, Maine, July 1984—to present

SOCIETY MEMBERSHIP

Pima County Pediatric Society	1963—1965
Sociedad Pediatricia de Trujillo	1956—1968

American Academy of Pediatrics	1968—to present
Medical Society of the District of Columbia	1969—1978
Society for Neuroscience	1970—1978
Maine Medical Association	1978—1980; 1986—to present

INVESTIGATIVE EXPERIENCE:

Two studies were carried out between 1961 and 1963, one concerning the laboratory diagnosis and clinical management of salicylate intoxication with gradation of severity and the other concerning the two-year residency experience with in-patients classified according to disease category. Between 1963 and 1965, clinical investigations were carried out relating to (1) epidemic infection with coxsackie A-16, (2) coccidioidomycosis, (3) the treatment of acute otitis media, and (4) the diagnosis and therapy of acute promazine intoxication.

Between 1965 and 1967, four studies were carried out in Peru regarding health conditions in a shanty-town community. These involved (1) the prevalence of diarrhea in infants and young children, (2) the nutritional state of infants and children between 6 months and 6 years of age, (3) the dietary habits of children under 15 years of age, and (4) the socio-economic and sanitary conditions of 100 families. An additional report was prepared concerning the introduction of family medicine concepts into the curriculum of the clinical years in a Latin American medical school.

Investigative activities from 1967 to 1977 involved (1) the development of diagnostic approaches to young children with learning or vision problems; (2) the implementation of interdisciplinary services for children with learning problems in health and public school settings; (3) the development of training programs subject to systematic evaluation for professionals and non-professionals working in child health and development areas; (4) planning and evaluation of large

scale health and child development services in school-aged children; and (5) the planning and evaluation of house officer curriculum in general pediatrics and child development.

Since 1978, focus has been on the introduction of health promotion education into school health programs and into the private practice of pediatrics and the design, implementation and evaluation of a developmental pediatrics curriculum for residents as chairperson of a national task force. Since 1982, investigations have included the effectiveness of early educational intervention for handicapped children and practical approaches to the prevention of developmental disabilities.

PUBLICATIONS (Articles):

1. Richardson, H.B., Jr., and Leibovitz, A.: Hand, foot and mouth disease in children: an epidemic associated with Coxsackie virus A-16, Journal of Pediatrics 67: 6-12, 1968.
2. Richardson, H.B., Jr., Anderson, J.A., and McKay, B.M., Acute pulmonary coccidioidemycosis in children. Journal of Pediatrics 70: 376-382, 1967.
3. Medina, T., Javier, and Richardson, H.B., Jr.: Estudio de diarrhea en una poblacion de barrriada; prevalencia en infantes y ninos menores y uso de un metodo de tratamiento standard. (Study of diarrhea in a shanty-town population; prevalence in infants and small children and use of a standard treatment method.) Transacciones del V Congreso Peruano de Pediatria (April, 1966).
4. Bartalos, M., and Richardson, H.B., Jr., Aneusomy by recombination: a possible example involving E-18 chromosome. Acta Genetica Medica et Gemellologiae (Rome) 18: 117-124, 1969.
5. Christopolos, Florence, Costenbader, Frank D., Goldberg, Herman K., Mills, Jack, and Richardson H. Burtt, Jr.,

Symposium on Dyslexia. Bulletin of the Washington Hospital Center. Vol. 1, 1: 5-25, 1970.

6. Richardson, H. Burtt, Jr., and Ozer, Mark N.: Diagnostic evaluation of children with learning problems: role of the pediatrician. Clinical Proceedings, Children's Hospital National Medical Center, Vol. 26: 119-125, 1970.

7. Ozer, Mark N., Richardson, H. Burtt, Jr., Tannhauser, Miriam, and Smith, Cora: Diagnostic evaluation of children with learning problems: An Interdisciplinary Clinic Model. Clinical Proceedings, Children's Hospital National Medical Center, Vol. 26: 166-177, 1970.

8. Ozer, Mark N., and Richardson, H. Burtt, Jr.: The diagnostic evaluation of children with learning problems: a communication process. Childhood Education 244-247, 1972.

9. Ozer, Mark N., and Richardson, H. Burtt, Jr.: The diagnostic evaluation of children with learning problems: a "process" approach. Journal of Learning Disabilities, 88-92, 1974.

10. Richardson, H. Burtt, Jr., Guralnick, Michael J., and Tupper, Deborah B.: Training pediatricians for effective involvement with handicapped preschool children and their families. Mental Retardation, Vol. 16, 1: 3-7, 1978.

11. Richardson, H. Burtt, Jr., and Guralnick, Michael J.: Pediatric residents and young handicapped children: curriculum evaluation. Journal of Medical Education, Vol. 53: 487-492, 1978.

12. Guralnick, Michael J., Richardson, H. Burtt Jr., and Heiser, Karen E.: A curriculum in handicapping conditions for pediatric residents. Exceptional Children, Vol. 48, 383-346, 1982.

13. Bennett, Forrest C., Guralnick, Michael J., Richardson, H. Burtt, Jr., and Heiser, Karen E.: Teaching developmental

pediatrics to residents: effectiveness of a structured curriculum. Pediatrics 74: 514-522, 1984.

14. Guralnick, Michael J., Bennett, Forrest C., Heiser, Karen E., and Richardson, H. Burtt, Jr., Training future primary care pediatricians to serve handicapped children and their families. Topics in Early Childhood Special Education, Vol 6: 1-11, 1987.

15. Guralnick, Michael J., Bennett, Forrest C., Heiser, Karen E., Richardson, H. Burtt, Jr., and Shibley, R.E., Jr.: Training residents in developmental pediatrics: results from a national replication. Journal of Development and Behavioral Pediatrics, Vol. 8: 260-265, 1987.

16. Guralnick, Michael J., Heiser, Karen E., Eaton, A.P., Bennett, Forrest C., and Richardson, H. Burtt, Jr., and Groom, J.M.: Pediatricians' perceptions of the effectiveness of early intervention for at-risk and handicapped children. Journal of Developmental and Behavioral Pediatrics, Vol. 9: 12-18, 1988.

PUBLICATIONS (BOOKS):

1. *Pediatric Education and The Needs of Exceptional Children.* Guralnick, Michael J., and Richardson, H. Burtt, Jr., (Editors). Baltimore: University Park Press, 1980.

PUBLICATIONS (CHAPTERS):

1. Richardson, H. Burtt, Jr.: Relationship of research to health and educational services. Chapter in *Early Experience and Visual Information Processing In Perceptual and Reading Disorders*. (F.A. Young and D.B. Lindsley, Eds.) Washington, National Academy of Sciences, 1970, pp. 467-473.

2. Ozer, Mark N., and Richardson, H. Burtt, Jr.: "Diagnosis" in relation to children with learning problems: the use of models. Chapter in *Cybernetics Technique in*

Brain Research and the Educational Process. Washington, D.C., American Society for Cybernetics, 1973, pp. 90-102.

3. Guralnick, Michael J., Richardson, H. Burtt, Jr., and Kutner, Douglas R.: Pediatric education and the development of exceptional children. Chapter in Guralnick, Michael J., and Richardson, H. Burtt, Jr., *Pediatric Education and The Needs of Exceptional Children*. Baltimore, University Park Press. 1980 pp. 2-19.

4. Richardson, H. Burtt, Jr., and Guralnick, Michael J.: An evaluation strategy for pediatric rotations on the needs of exceptional children. Chapter in Guralnick, Michael J., and Richardson, H. Burtt, Jr., *Pediatric Education and the Needs of Exceptional Children*. Baltimore, University Park Press, 1980, pp. 129-135.

5. Richardson, H. Burtt, Jr., Guralnick, Michael J., Taft, Lawrence T., and Levine, Melvin D.: A comprehensive curriculum in child development and handicapping conditions. Prospects for design, implementation and evaluation. Chapter in Guralnick, Michael J., and Richardson, H. Burtt, Jr., *Pediatric Education and the Needs of Exceptional Children*. Baltimore, University Park Press, 1980. pp. 185-202.

6. Richardson, H. Brutt, Jr., and Guralnick, Michael J.: Physician education in developmental-behavioral pediatrics. Chapter in Levine, Melvin D., et al., *Developmental-Behavioral Pediatrics*. Philadelphia, W.B. Saunders and Co., 1983, pp. 1210-1219.

7. Richardson, H. Burtt, Jr.: Pediatrics and developmental disabilities: the state of the art in pediatrics. Chapter in *Alliances in Health and Education for Disabled Children and Youth: Directions for the 80's*. Washington, D.C., American Society of Allied Health Professionals 1983.

8. Guralnick, Michael J., Heiser, Karen E., Bennett, Forrest C., and Richardson, H. Burtt, Jr.: A systems approach to training pediatricians in the field of developmental disabilities. In M.D. Powers (Ed.), *Severe Developmental Disabilities: Expanded Systems of Interaction.* Baltimore, Brookes. 1987, pp. 255-271.

9. Bennett, Forrest C., Guralnick, Michael J., Heiser, Karen E., and Richardson, H. Burtt, Jr.: Training in developmental pediatrics. In M.L. Wolraich and D.K. Routh (Eds.), *Advances in Developmental and Behavioral Pediatrics.* (Vol. 8) Greenwich, CT: JAI Press. 1987, pp. 99-124.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA

Plaintiff

v. Civil Action No.
00-157-B

KEVIN CONCANNON, in his official
capacity as Commissioner of the
Department of Human Services
For the State of Maine
and
ANDREW KETTERER, in his official
capacity as Attorney General
For the State of Maine

Defendants.

AFFIDAVIT OF KEVIN CONCANNON

KEVIN CONCANNON, being duly sworn, deposes and says that the following is true and correct and based upon personal knowledge:

1) My name is Kevin Concannon. I am the Commissioner of the State of Maine Department of Human Services (the "Department"). I submit this affidavit in opposition to the plaintiff's motion for a preliminary injunction in the above-captioned action.

2) Title 22 M.R.S.A. §2681, et seq., assigns to the Department the responsibility of administering the newly enacted Maine Rx Program, a program designed to make prescription drugs more affordable for residents of Maine who do not otherwise have prescription drug benefits through

private insurance or public medical assistance programs. The program will commence on January 1, 2001.

3) While the precise number of Maine residents who will be eligible to enroll in the Maine Rx Program is not known at this time, the current Department estimate is that 325,000 persons may be eligible to enroll in the program.

4) Title 22 M.R.S.A. §2681(4) instructs the Commissioner of the Department to negotiate with drug manufacturers and labelers for drug rebates to be paid into the Maine Rx Program. In furtherance of that mandate, on August 2, 2000 I sent the Department's proposed Maine Rx Program Rebate Agreement ("Rebate Agreement") to manufacturers of prescription drugs. A copy of the Rebate Agreement is attached to this affidavit as exhibit A.

5) As is set forth in Section II of the Rebate Agreement, the first Maine Rx Program rebate payment from participating manufacturers, for drugs dispensed through the program during the first quarter of its operation will be due no earlier than September 30, 2001.

6) As of today, twenty-seven (27) prescription drug manufacturers have elected to participate in the Maine Rx Program by executing Maine Rx Program Rebate Agreements.

7) The Bureau of Medical Services is the branch of the Maine Department of Human Services charged with overseeing and administering the Medicaid Program.

8) 22 M.R.S.A. §2681(7) instructs the Department to impose prior authorization requirements in the Medicaid program, as permitted by law, for the dispensing of prescription drugs provided by manufacturers and labelers which do not enter into Maine Rx Rebate Agreements.

9) The Department will not impose a prior authorization requirement in the Medicaid program, pursuant to 22 M.R.S.A. §2681(7), where the imposition of such a

requirement would conflict with the requirements of the Medicaid program. Prior authorization requirements will not be implemented so as to prevent Medicaid recipients from obtaining medically necessary prescription drugs.

10) The Department is in the process of drafting administrative rules for the Maine Rx Program and drafting proposed amendments to the Medicaid rules. These new rules, and rule amendments, will be proposed according to the procedures set forth in the State of Maine Administrative Procedures Act. A copy of the current draft of the portion of the rules involving implementation of Maine Rx Program "prior authorization" provision are attached to this affidavit as exhibit B.

11) Pursuant to these proposed rules, Maine's Medicaid Drug Utilization Review Committee ("DUR Committee"), an advisory board comprised of physicians and pharmacists who are licensed to prescribe or dispense medications in Maine, will make the final determination of the clinical appropriateness of any recommendation that a prior authorization requirement be imposed with respect to a particular prescription drug manufactured by a manufacturer which has not entered into a Maine Rx Rebate Agreement. In making its determination of whether or not a prior authorization requirement is clinically appropriate, the DUR Committee shall be guided by the law of Medicaid, and particularly the principle that Medicaid recipients shall be assured access to all medically necessary prescription drugs.

12) The State of Maine purchases large quantities of prescription drugs on behalf of Medicaid recipients. A chart prepared by the Department which summarizes the State's drug purchasing activity in the Medicaid program over that last three fiscal years is attached to this affidavit as exhibit C.

Dated: September 8, 2000

/s/
KEVIN CONCANNON, COMMISSIONER

STATE OF MAINE
KENNEBEC, ss

Before me this day personally appeared Kevin Concannon, who being duly sworn, deposes and says that the statements in the above affidavit of same, are true.

/s/ Marie Lahaye
Name of Notary Public
Notary Public, State of Maine
My Commission Expires: 1-5-2005

[Exhibit A]

MAINE RX PROGRAM REBATE AGREEMENT

BETWEEN

THE COMMISSIONER OF THE DEPARTMENT OF HUMAN SERVICES OF THE STATEOF MAINE

AND

THE MANUFACTURER IDENTIFIED IN SECTION VIII

OF THIS AGREEMENT

(Hereinafter referred to as the "Manufacturer")

The Commissioner, on behalf of the State of Maine, and the Manufacturer, on its own behalf for the purposes of complying with Public Law 1999, chapter 786, hereby agree to the following:

I. DEFINITIONS

The terms defined in this section will, for the purposes of this Agreement, have the meanings specified herein:

(a) "*AVERAGE WHOLESALE PRICE*" means the Wholesale Price charged on a specific commodity that is assigned by the drug Manufacturer and is listed in a nationally recognized drug-pricing file.

(b) "*CALENDAR QUARTER*" means four times a year. Specifically the first Calendar Quarter will be from January 1, 2001 — March 31, 2001. Each successive three-month period shall be a Calendar Quarter.

(c) "*COMMISSIONER*" means the Commissioner of the Department of Human Services.

(d) "*DEPARTMENT*" means the Department of Human Services.

(e) "*MANUFACTURER*" means the entity holding legal title or possession of the National Drug Code (NDC) for the Prescription Drug.

(f) "*NATIONAL DRUG CODE* (NDC)" is the identifying drug number maintained by the Food and Drug Administration (FDA). For the purposes of this Agreement, the complete 11-digit NDC will be used including the labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specific product or -formulation), and package size code to identify a prescription drug.

(g) "*NET SALES*" means Calendar Quarter gross sales revenue less cash discounts allowed and all other price reductions which reduce the actual price paid; and as discussed under the definition of WP.

(h) "*PRESCRIPTION DRUG*" means (1) legend drugs, defined as drugs carrying the statement "Caution: Federal Law Prohibits Dispensing Without A Prescription" and (2) any other drugs which by State law or regulation require the prescription of a licensed practitioner for dispensing. For purposes of this Agreement, all Prescription Drugs must be identified by the Manufacturer's labeler code segment of the National Drug Code (NDC).

(i) "*QUALIFIED RESIDENT*" means a resident of the State who has obtained from the Department a Maine Rx enrollment card.

(j) "*REBATE AMOUNT*" means the Medicaid Rebate amount.

(k) "*REBATE PAYMENT*" means, with respect to the Manufacturer's Prescription Drugs, the Calendar Quarter payment by the Manufacturer to the State of Maine which shall be the sum of the Rebates of each prescription drug (computed for each dosage form and strength of each Prescription Drug) calculated as follows:

(1) The total number of Units paid under the Maine Rx Program for qualified residents during the Calendar Quarter multiplied by the Rebate amount per Unit.

(2) Effective January 1, 2001, a percentage equal to the Medicaid Rebate percentage to the State of Maine in effect for the corresponding time period.

(l) "*UNIT*" means drug Unit in the lowest identifiable amount (i.e. tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams). The Manufacturer will specify the Unit for each dosage form and strength of each Prescription Drug in accordance with instructions developed by the Health Care Financing Administration for purposes of the Federal Medicaid Rebate program under Section 1927 of the Social Security Act.

(m) "*UTILIZATION DATA*" means the information regarding the total number of Units of each dosage form and strength of the Manufacturer's Prescription Drugs paid during the Calendar Quarter under the Program. Drugs dispensed prior to January 1, 2001 are excluded. The Utilization Data includes: (1) 11-digit NDC, including package size code; (2) product name; (3) quantity of Units paid during the Calendar Quarter by 11-digit NDC; (4) total number of prescriptions paid during the Calendar Quarter by 11-digit NDC; and (5) total dollar amount paid during the Calendar Quarter by 11-digit NDC.

(n) "*WHOLESALE PRICE* (WP)" means, with respect to a Prescription Drug of the Manufacturer for a Calendar Quarter the average price paid by Wholesalers in the United States to the Manufacturer, for ultimate distribution to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to Wholesalers where the drug is relabeled under that distributor's national drug code). WP includes cash discounts allowed and all other price reductions, which reduce the actual price paid. It is calculated as a weighted average of prices for a Manufacturer's package sizes for each Prescription Drug by the Manufacturer during that Calendar Quarter. Specifically it is calculated as Net Sales divided by number of Units sold, excluding drugs or any other items given away but not contingent on any purchase requirements. For bundled sales, the allocation of the discount is made proportionately to the dollar value of the Units of each drug sold under the bundled arrangement. The V/P for a Calendar Quarter must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjusted the prices actually realized.

(o) "*WHOLESALER*" means any entity (including a pharmacy or chain of pharmacies) to which the Manufacturer sells the Prescription Drug, but that does not re-label or repackage the Prescription Drug.

II. MANUFACTURER'S RESPONSIBILITIES

The Manufacturer agrees to the following:

(a) To calculate and to make a Rebate Payment each Calendar Quarter to the State of Maine for the Manufacturer's Prescription Drugs paid for by the Department pursuant to the Maine Rx Program during a Calendar Quarter under the Maine Rx Program as follows:

Manufacturer's first rebate payment for the Calendar Quarter January 1, 2001 through March 31, 2001 shall be due September 30, 2001, or 30 days after receipt of utilization data pursuant to Section III (a) of this Agreement, whichever is later.

All subsequent Rebate payments will be made by the Manufacturer to the State of Maine within 30 days of the close of each Calendar Quarter, or within 30 days upon receipt of the Utilization. Data pursuant to Section III (a) of this Agreement, whichever is later. Simultaneously, with each Rebate Payment, the Manufacturer will provide the Department with the Manufacturer's most recent price catalog, unless no price changes were made from the previous Calendar Quarter.

(b) To continue to make a Rebate Payment to the State of Maine on all of its Prescription Drugs as defined in this Agreement so long as this Agreement, or a successor Agreement, is in force and as long as such Prescription Drugs are dispensed under the Manufacturer's NDC. If there are no sales by the Manufacturer during a Calendar Quarter the WP used for the most recent Calendar Quarter in which sales occurred will continue to be used in calculating Rebates.

(c) The Manufacturer will be responsible for Rebates on claims for prescription drugs that were dispensed within one year of the date that the claim was paid by the Department.

(d) The Manufacturer agrees to maintain all books, documents, papers, accounting records, and any other evidence pertaining to this Agreement and make such material available at its offices during normal business hours and shall send copies of such material to the Department upon the request of the Department during the period of this Agreement and for a period of two years after the termination of this Agreement. The

Manufacturer shall allow inspection of pertinent documents by the Department or any authorized representative of the State of Maine, and shall furnish copies thereof, if requested.

III. COMMISSIONER'S RIGHTS AND RESPONSIBILITIES

(a) The Department, on behalf of the Commissioner, shall send the Utilization Data as defined in this Agreement, to the Manufacturer, by certified mail, return receipt requested, within 60 days following the last day of each Calendar Quarter for qualified residents. The Commissioner, through the Department, shall maintain electronic claims records for the most recent four Calendar Quarters that will permit the Manufacturer to verify through an audit process The Utilization Data provided by the Department.

(b) The Department shall conduct audits, as it deems necessary to verify rebate calculation and payment.

IV. DISPUTE RESOLUTION FOR DISCREPANCIES IN REBATE AMOUNTS

Discrepancies in Rebate amounts must be resolved using the following process:

(a) If there is a discrepancy in the Manufacturer's or labeler's favor between the amount claimed by a pharmacy and the amount rebated by the Manufacturer or labeler, the Department, at the Department's expense, may hire a mutually agreed-upon auditor. If a discrepancy still exists following the audit, the Manufacturer or labeler shall justify the reason for the discrepancy or make payment to the Department for any additional amount due.

(b) If there is a discrepancy against the interest of the Manufacturer or labeler in the information provided by the Department to the Manufacturer or labeler regarding

the Manufacturer's or labeler's Rebate, the Manufacturer or labeler, at the Manufacturer's or labeler's expense, may hire a mutually agreed-upon independent auditor to verify the accuracy of the data supplied to the Department. If a discrepancy still exists following the audit, the Department shall justify the reason for the discrepancy or refund to the Manufacturer any excess payment made by the Manufacturer or labeler.

(c) Following the procedures established in paragraph a or b, either the Department or the Manufacturer or labeler may request a hearing before the Department of Human Services Administrative Hearings Unit. Supporting documentation must accompany the request for a hearing.

(d) The Manufacturer further agrees that the sole and exclusive means for the presentation of any legal claim against the State arising out of this Agreement shall be in accordance with 5 MRSA section 11001. The Manufacturer further covenants not to initiate legal proceedings in any State or Federal court in addition to, or in lieu of, proceedings under section 11001. This Agreement shall be governed in all respects by the laws, statutes, and regulations of the United States of America and of the State of Maine. The Manufacturer consents to personal jurisdiction in the State of Maine.

(e) Nothing herein shall be construed or interpreted as limiting or otherwise affecting the Department's ability to pursue its rights arising out of the terms and conditions of the Agreement in the event that a dispute between the parties is not otherwise resolved.

V. CONFIDENTIALITY PROVISIONS

(a) Commercial or financial information disclosed by the Manufacturer in connection with this Agreement is confidential information, and will not be disclosed by the Commissioner or the Department (including any

auditors or agents thereof) in a form which discloses the identity of a specific Manufacturer or Wholesaler, prices charged for drugs by such Manufacturer or Wholesaler, in accordance with 42 U.S.C. § 1396r-8(b)(3)(D), 22 M.R.S.A. § 402(3) and Maine Rules of Evidence, Rule 507.

(b) The Manufacturer will guarantee the protection and confidentiality of the Utilization Date, including the proper care, custody, use and preservation of records, papers, files, communications of the Department and any other information that may reveal information related to the Utilization Data. If the Manufacturer audits this information or receives further information on such data, that information shall also be held confidential. The Manufacturer shall have the right to disclose Utilization Data to auditors who agree to keep such information confidential.

(c) Notwithstanding the non-renewal or termination of the Agreement for any reason, the confidentiality provisions will remain in full force and effect.

VI. TERMINATION

(a) Unless otherwise terminated by either party pursuant to the terms of this Agreement, the Agreement shall be effective for an indefinite period beginning on January 1, 2001.

(b) The Manufacturer may terminate the Agreement for any reason, and such termination shall become effective the first day of the first Calendar Quarter period beginning sixty (60) days after the Manufacturer gives written notice requesting termination.

(c) The Commissioner may terminate the Agreement for any reason, upon sixty- (60) days prior written notice to the Manufacturer.

(d) The termination of this Agreement by either party will not affect any Rebate payments due to the State of Maine.

(e) In the event that any element of this Agreement is affected by a legislative amendment, including, but not limited to the percentage amount of Rebate required, such amended or revised provisions shall be incorporated by reference within this Agreement and shall supersede any of the conflicting provisions of this Agreement. If either party is unwilling to accept such a change in terms, this Agreement may be terminated pursuant to the terms set out in subsections (a) through (d) above.

VII. GENERAL PROVISIONS

(a) Any notice required to be given pursuant to the terms and provisions of this Agreement will be sent in writing.

Notice to the Commissioner will be sent to:

Maine Rx Program
Director of Pharmacy Programs
Bureau of Medical Services, 3rd Floor
11 State House Station
Augusta, ME 04333-0011

Notice to the Manufacturer will be sent to the address provided to the Department by the Manufacturer.

(b) In the event of a transfer of ownership of the Manufacturer, this Agreement is automatically assigned to the new owner subject to the conditions specified in this Agreement.

(c) Nothing in this Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of the Agreement is found to be invalid by a court of law, this Agreement will be construed in all respects as if any invalid or unenforceable provision

were eliminated, without any effect on any other provision.

(d) Nothing in this Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Commissioner under the Constitution, the Social Security Act, other Federal laws or State laws.

(e) The terms "Department: and "Manufacturer" incorporate any contractors or agents thereof, which fulfill responsibilities pursuant to this Agreement unless specifically provided for in the Rebate Agreement.

(f) This Agreement will not be altered except by an amendment in writing signed by both parties and except as indicated in subsection VI (e). No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by a duly appointed representative of the Manufacturer, and the Commissioner, and approved by the Office of the Attorney General.

(g) In the event that a due date falls on a weekend, or a Federal or State holiday, the report or other item will be due on the first business day following that weekend or holiday.

VIII. MANUFACTURER'S ACCEPTANCE

I, _____ hereby agree to the terms
(Name of Authorized Representative)
of this Agreement for the following Manufacturer(s) and labeler(s):

_____	_____
(Labeler Name)	(Code)
_____	_____
(Labeler Name)	(Code)

_____	_____
(Labeler Name)	(Code)
_____	_____
(Labeler Name)	(Code)
_____	_____
(Signature)	(Title)

Date: _____

[Exhibit B]

Maine Rx Program
Draft Proposed Rule for Prior Authorization Provision
9/00

"Drugs of non-participating drug manufacturers shall be reviewed by the Department as to the clinical appropriateness of prior authorization for those drugs. Recommendations to prior authorize any of those drugs shall be referred to the Medicaid Drug Utilization Committee, for a final determination of whether those drugs should be prior authorized, in accordance with federal and state law. In all instances, Medicaid recipients shall be assured access to all medically necessary outpatient drugs."

Maine Medical Assistance Manual, Section 80 (Pharmacy Services)
Draft Proposed Rule for Prior Authorization Provision 9/00

Amend Rule 80.01-7 (new words are underlined).

"Drug Utilization Review Committee means an advisory committee to the Medicaid Program, comprised of physicians and pharmacists, who are licensed to prescribe or dispense medications in Maine."

Propose New Rule:

"The Drug Utilization Review Committee shall consider and make the final determination regarding the clinical appropriateness of all prior authorization recommendations, including those concerning drug manufacturers who do not participate in the Maine Rx Program. In all instances, Medicaid recipients shall be assured access to all medically necessary outpatient drugs."

[Exhibit C]

Medicaid Outpatient Prescription Drug Spending

	SFY 97	SFY 98	Chg	SFY 99	Chg
Gross Expenditures	$98,964,628	$109,697,688	10.8%	$135,493,928	23.5%
Drug Rebates	-$17,206,484	-$20,206,046	17.4%	-$27,957,863	38.4%
Net Expenditures	$81,758,144	$89,491,642	9.5%	$107,536,065	20.2%
Drug Rebate Percentage	17.4%	18.4%		20.6%	
Number of Drug Recipients	141,220	144,205	2.1%	148,654	3.1%
Gross Exp Per Recipient	$700.78	$760.71	8.6%	$911.47	19.8%
Net Exp Per Recipient	$578.94	$620.59	7.2%	$723.40	16.6%
Number of Prescriptions	2,793,666	2,870,422	2.7%	3,114,155	8.5%
Prescriptions per Recipient	19.8	19.9	0.6%	20.9	5.2%
Expenditures per Prescription	$35.42	$38.22	7.9%	$43.51	13.8%

November 29, 1999, Christopher Nolan, Bureau of Medical Services, Department of Human Services

UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH, of AMERICA — CIVIL ACTION

Plaintiff — Docket No. 00-157 B-H

v

COMMISSIONER, Maine Dept of Human Services

Defendant

Transcript of Proceedings

Hearing on Preliminary Injunction before HON. D. BROCK HORNBY in the United States District Court, Edward T. Gignoux Courthouse, 156 Federal Street, Portland, Maine, on the 19th day of October 2000 as follows:

Appearances:

For the Plaintiff: Bruce C. Gerrity, Esq.
Preti, Flaherty, Beliveau
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Transcript recorded by mechanical stenography, transcript produced by computer aided transcript.

(Transcript of hearing on motion for preliminary injunction before HON. D. BROCK HORNBY in the United States District Court, Edward T. Gignoux U.S. Courthouse, Portland, Maine, on the 19th day of October 2000 beginning at 9:00 AM as follows:)

THE COURT: Good morning. (Counsel responded).

The matter on for hearing is civil number 00-157 P-H, Pharmaceutical Research Manufacturers of America versus the Commissioner of Maine Department Human Services et al. And the matter is on this morning for a hearing on the plaintiff's motion for preliminary injunction. I know there's a wide degree of interest in this case and let me, therefore, just summarize a couple of things that the lawyers already know.

I did hold a telephone conference with the lawyers two days ago, I guess it was, counsel, at my request. The reason for the telephone conference is that the preliminary injunction issue is going based upon affidavits and arguments presented in writing, and the arguments made here this morning. I was inquiring of the lawyers whether it was possible to consolidate into one hearing all of the factual issues that might be present in the lawsuit. That is something that a Federal Court can do under Rule 65, under appropriate circumstances.

As a result of the telephone conference, however, I concluded that it would be premature to do that and so the hearing is going forward on the original premise, which is to say my decision will be based upon the written submissions consistent with the legal arguments, affidavits, legislative materials and things of that sort.

I will also say at the outset that I will not decide the case today. I will hear the arguments. This is a complex matter. I will issue a written decision after I've had the opportunity to digest things I hear this morning. I have read everything submitted. By the way, counsel, I received everything that

each of you submitted in the last day, both the state and the plaintiff, proposed and legislative debate.

The final thing I will say before I hear argument, just an explanation of a couple of terms for the benefit of people in the audience.

I think everyone knows that there are constitutional issues being raised here, and under the federal constitution there is a provision called the Interstate Commerce clause that in Article 1 section 8 of the constitution says, Congress shall have power to regulate commerce with foreign nations, and among the several States, and with the Indian Tribes.

There is a doctrine, and you will probably hear the lawyers refer to it, this is why I want to mention it, called the Dormant Congress Clause. This is a term that only lawyers would understand, that's why I mention it. The theory is, the doctrine is even when Congress does not actually exercise its power to regulate commerce, under Article 1 section 8, that there is a dormant power there which, in some circumstances, even in the absence of regulation, a state cannot threaten that theory, and you will probably hear reference to it in discussion.

The other provision that is at issue is Article 6 of the Constitution that says: This Constitution, and the LAWS of the United States which shall be made in Pursuance thereof, and all Treaties made, or which shall be made, under the authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

That is often called the Supremacy Clause. And there will be argument here today as to whether the Supremacy Clause has any effect on any law.

I just announced that for the benefit of the reporters that might not understand the language being used.

Mr. Gerrity, I will ask you to introduce your co-counsel.

MR. GERRITY: Thank you, your Honor. If I could, I would introduce the Court to Allen Rugg of Powell, Goldstein, Frazier & Murphy. Mr. Rugg will be presenting the oral argument today. With him is Marin Carlson, also of his firm and Daniel Price, who is here as well.

THE COURT: Thank you. Before you start, Mr. Hagler, do you want to introduce your group?

MR. HAGLER: Yes, thank you, your Honor. With me from the attorney general's office is John Brautigam, and also Cab Howard, whom the state is pleased to have join us in these proceedings. I will be arguing the case your Honor.

THE COURT: Thank you. Mr. Rugg, I'll hear you.

MR. RUGG: Thank you very much, your Honor. It is an honor to appear before the Court and we appreciate the Court's scheduling this argument on Pharmaceutical's motion for Preliminary Injunction.

As the Court is aware, the relief that PhRMA is seeking is an immediate Preliminary Injunction restraining the implementation and the enforcement of the Maine Rx program and the related antiprofiteering section of the statute. It is our contention that those statutes violate the constitution with regard to the Commerce Clause, and with regard to the sanction of requiring prior authorization in the unrelated Maine Medicaid program that the statute violates the Supremacy Clause.

Your Honor, the member companies of PhRMA are at immediate risk and will face irreparable injury absent relief from this court. The state is presently implementing this statute. The implementation began on August 2nd, a week before the effective date of the statute.

Presently our member companies have a deadline to respond to the Commissioner's request that they execute rebate agreements by November 1st.

Interestingly, I read in the Wall Street Journal two days ago that Mr. Concannon has announced that after November 1st he intends to take out newspaper ads publicizing the names of companies that have elected not to execute the agreements. We understand that at that time, after November 1st, the companies will be at risk to have their prescription drugs that are distributed to Maine Medicaid recipients subject for the first time to prior authorization.

The record in this case is absolutely unchallenged as to the impact of such prior authorization, on the manufacturers. There is potentially a dispute in this case as to the impact on Medicaid recipients, and I will certainly address that. But for purposes of evaluating the standards for the issuance of a Preliminary Injunction, there is no question that prior authorization will work an immediate irreparable injury to the companies, and I specifically invite the Court's attention to the unchallenged declaration of Dr. Moules from Smith/Kline Beecham.

Let me pause just a moment here. I don't want to misspeak but there are portions of the Moules declaration that are subject to disagreement. When I say that it is undisputed, I'm addressing the portion of his declaration that describes the impact on companies when prior authorization is imposed, and specifically historical data of the impact on market share and sales of four specific drugs.

So, the impact is immediate and it should come as no surprise because when this statute was considered in the legislature, Senator Pingree, and in this legislative history that we just submitted to the Court which just became available to us, Senator Pingree stated if companies do not participate in this program, they will not be able to participate in Medicaid. And that the full, all the tools of the statute will be brought to

bear on companies to compel them to participate in this program.

Commissioner Concannon followed up on that, as I say, a week before the statute even became effective by requesting that the parties immediately execute rebate agreements.

Your Honor, if I may, I would like to address the likelihood of success on the constitutional challenges to the statute. With regard to the Maine Rx rebate, our principal argument, your Honor, is that Maine seeks to regulate out-of-state transactions. I would urge the Court to consider the declaration of Judith Tempel, who is Manager of Distribution Operations of Eli Lilly, that declaration is also unchallenged. Ms. Tempel reports that on August 4th, Ely Lilly in its headquarters in Indianapolis received a letter from Commissioner Concannon. The letter said, "Sign the enclosed rebate agreement. And if you don't, be aware of the antiprofiteering sections of the statute, the prior authorization sanction."

So, when you turn, and this is an exhibit to Ms. Tempel's declaration. When you turn to the proposed rebate agreement, it makes very clear that the state seeks to regulate and receive a payment from Eli Lilly in Indianapolis, Indiana for each prescription pill of Eli Lilly that crosses the counter of a pharmacist here in Maine. That is the only construction possible of the proposed rebate agreement.

I would ask the Court to then consider Ms. Tempel's declaration. Eli Lilly does not manufacture its drugs here in Maine.

It sells its drugs through warehouses in Connecticut, Indiana, and California.

It sells those drugs by distributors and manufacturers coming to Eli Lilly, negotiating arms length purchases of those drugs, which are not identified for shipment to any location in the United States. Pursuant to the agreement

between Lilly and the distributors, title passes at the warehouses, all outside of the State of Maine. And then, finally, the purchaser makes payment to Eli Lilly in Pittsburgh Pennsylvania. What is conspicuous is the absence of any act in this process that occurs in the State of Maine.

The distributors then selling, but the purpose and the effect of the rebate agreement is to change those transactions that occur in Pennsylvania, Indiana and California, changing the economics of Lilly's sales transactions, and taking money out of that transaction and moving it to Maine.

Your Honor, please, we submit that that evidence is unchallenged, uncontroverted and for very good reason.

There is one distributor that does business here in Maine, Bindery Western. A number of our member companies do some business with them, but the vast majority of the prescription medications that are sold here in Maine come to Maine through third-party distributor or wholesale. And we submit to the Court that we believe that's why this portion of our case is uncontroverted by the state. The state realizes that is the true factual record. And then we presume, we will argue to the Court that nevertheless, even though these transactions occur out of state, this statute, for some reason does not directly regulate those transactions.

THE COURT: I'm not sure what you're saying here. Are you saying that it can't apply to Bindery, or whatever that is, but not the others?

MR. RUGG: We think it could. We are submitting to the Court with regard to extraterritoriality argument, we would ask the Court to determine that to the extent that sales occur and are consummated outside the State of Maine, the statute cannot constitutionally regulate those transactions.

THE COURT: Let me press you on that language, outside the State of Maine, you told me, as you characterize it, in the vast majority of cases it's a transaction between a seller and a

distributor both of whom are located outside of Maine and title passes outside of Maine?

MR. RUGG: Yes sir.

THE COURT: You say there are a small portion of cases where a distributor is in Maine, and are you saying that title passes there in Maine? Outside of Maine? Does it matter? What is your contention there?

MR. RUGG: What we are contending is to the extent the transaction is concluded in Maine, if title transfers and the Bindering transaction, if you will, that occurs in Maine, we respectfully submit that our extraterritoriality argument would not attach to those transactions.

Of course, we persist in our contention that the benchmarking problems under the Commerce Clause would still apply to those transactions.

Your Honor, with regard to this extraterritoriality issue, we submit that the legal authorities are clear, that Maine simply has no authority to go beyond its borders to exercise regulation of transactions in other states.

If your Honor please, I would like to turn to the benchmarking argument.

THE COURT: Go ahead.

MR. RUGG: The statute—let me back up. In August when this statute was considered, the clear argument before the senate was the manufacturers would be required to initially provide the Medicaid rebate to Maine residents. That's the force also of Commissioner Concannon' s letter of August 2nd.

The Medicaid rebate amount, under the Medicaid program, is provided by statute. And in general terms, it is the greater of 15.1 percent less than the average manufacturer's price, or the spread between the average manufacturer's price and the manufacturer's best commercial price.

Now, understandably there is a lot of federal regulation but that's the basic formula. What is critical for today's purposes, that is not a statutory number, it is a statutory formula, that is applied on an ongoing basis and is driven by economic market transactions all over the United States. So, if a manufacturer who is participating in Medicaid decides to offer a best price to a commercial customer in Colorado, that affects the Medicaid rebate, Medicaid is a national consensual program, manufacturers make a decision whether they want to participate in Maine Medicaid or whether they want to participate in Medicaid nationwide.

So manufacturers having made that decision understand that market transactions that they enter into affects the Medicaid price.

This statute seeks to exploit that Medicaid calculation for purposes totally unrelated to Medicaid, for the sole purpose of driving down prices of prescription drugs for citizens of Maine. There is no Medicaid interest here, it is simply, you are borrowing the formula and applying it in this state's statute.

What's crucial for the benchmarking analysis is that with this statute, prices in Maine are linked or indexed to prices that are made in market transactions entirely outside of Maine. And we urge the Court to consider the application of *Sealig and Healy* because we think that this statute in effect is quite analogous to the price affirmation statute, for example, that was the subject of the *HEALY* case.

Your Honor, I'd like to turn to the consideration of the sanction of prior authorization.

When we had our telephone conference hearing two days ago we had some discussion of whether there would be issues of fact related to this issue. And our representations to the Court were that we think this is really a legal question. And the legal question, your Honor, I alluded to it earlier, is whether without violating the Supremacy Clause of the

United States Constitution can Maine borrow or take the Medicaid formula and apply it in this case. And if it does, is the vehicle for driving it, namely prior authorization in unrelated programs, consistent with the Supremacy Clause.

THE COURT: I take it by the thrust of your argument that you are agreeing that the publicity requirement alone would not be a sanction that violates the Supremacy Clause.

MR. RUGG: Your Honor, that is correct, we do not contend that that is a violation of the Supremacy Clause.

THE COURT: Or even the Commerce Clause?

MR. RUGG: No, but we think—I'm sorry, to be clear, I agree with the Court. But we think the publicity sanction is important for applying the Preliminary Injunction standard.

THE COURT: I understand.

MR. RUGG: Okay. Your Honor, the nub of the Supremacy argument is that Medicaid prior authorization becomes a tool or a weapon to coerce participation in the Maine program. There can be no mistake that the state recognizes this. When Senator Pingree states, if in fact the manufacturers choose not to cooperate, we will use all the tools available to us here in the State. We will require their participation in this program if they want to participate in the Medicaid program. If they want to participate in the National Medicaid Program, they have to participate in this Maine program. That is what the Senator said, and that is clearly the purpose of the prior authorization sanction in this statute.

And today as we sit here, that is the weapon that is waiving around.

It's the weapon that Commissioner Concannon built August 2 letter.

It is the subject, when he is interviewed in the press, it's the weapon that he invokes.

THE COURT: Whether Senator Pingree said that or not, there is nothing in the statute that takes the manufacturer out of the Medicaid, it is limited to prior authorization if they choose not to comply with the Maine Rx.

MR. RUGG: The statute simply provides that it is not discretionary, that the state shall prior authorize the manufacturer's drugs if they do not participate.

THE COURT: So the question is the bite of that the state

into his provision as—

MR. RUGG: Right. Now, I'm concerned that since, at a very high level we are talking about prescription drugs. We could jump to the conclusion that prior authorization in Medicaid is really quite consistent with prior authorization under the Maine statute.

If your Honor please, let's imagine it's January, next January, and let's assume that certain manufacturers have not participated, for the first time, even though Maine has participated in Medicaid for many years, and has utilized prior authorization for Medicaid purposes, by the force of this statute, manufacturer's drugs are prior authorized for the first time. What has changed?

Has the clinical research changed?

Has the medical literature changed?

Has the assessment of patient need changed?

What has changed is that this statute has become effective and the weapon, the coercive weapon is being brought to bear.

Now, I would like to suggest one other possible way of looking at this. Let's suppose that this statute says that the manufacturer shall make rebate payments, and that the state shall use these rebate payments for elementary school education or for building roads, or dredging the harbor. And

the weapon to coerce this participation is prior submitted authorization.

I think under that scenario there would be no debate as to whether the prior authorization under the Medicaid statute was being used improperly for an unrelated state purpose, and the result being an obstacle and a burden to the realization of the goals of the federal program.

Finally, on this point, we note the declaration by Maine.

The board that will be making these decisions has in the past been making Medicaid decisions. The resources and the personnel who have traditionally implemented Medicaid are suddenly being charged with the responsibility of implementing a very narrow specific state statute.

THE COURT: Let's be precise on the Supremacy—

MR. RUGG: Yes sir.

THE COURT: —argument. Congress has not specifically said this is prohibited, has it?

MR. RUGG: Has not.

THE COURT: So to respond to the attorney general's argument that there are two requirements for prior authorization—

MR. RUGG: Correct.

THE COURT: —being met.

MR. RUGG: That is correct. We do not base this argument on the provision of the Medicaid statute.

THE COURT: What do I have by way of a Chevron type analysis as to whether the Secretary of Health Human Services, or the Health Care Financial Administration or anyone else has given any kind of interpretation?

MR. RUGG: Draft regulations are in the process.

THE COURT: You are referring to state regulations; are you not?

MR. RUGG: Federal.

THE COURT: Tell me about that.

MR. RUGG: I want to be precise, your Honor. My recollection is that the proposed regulations would limit the use of prior authorization for implementation of the Federal Medicaid program but to be absolutely precise, your Honor, I would like to have the ability to follow-up on that.

THE COURT: Actually if you can in writing give me a federal register or citation.

MR. RUGG: We would be happy to.

If I may follow up on the Court's observation, recognizing that the only language in the statute dealing with prior authorization imposes conditions of the use of prior authorization that are of course consistent with its operation of the Medicaid program, I believe its availability of drugs on a 24-hour basis.

The statute does not address the utilization of prior authorization to enforce a totally unrelated statute. And we would submit to the Court perhaps the reason for that is that it would never occur to Congress that a Medicaid statute would be used as the coercive enforcement tool in a totally unrelated purpose. Take my example, if you will, of a program to fund education here in Maine, or roads here in Maine, would you expect the statute to say Medicaid prior authorization cannot be used as a vehicle to enforce contributions to the—fund in Maine. I think the only reason this becomes a narrower issue is, as I said earlier, perhaps at one level one could try to reconcile the federal Medicaid program and the state program as being a consistent common program but these are different populations, different agendas. And what's crucial is the Medicaid program is indeed a national program.

Finally, your Honor, with regard to the likelihood of success on the merits, I'd like to address the antiprofiteering portion of the statute.

THE COURT: Are you going to address the market participation?

MR. RUGG: I would be happy to. Let me do that right now. Our view is that the State of Maine is not participating in this program in a proprietary sense as either a purchaser or seller of drugs. This is classical regulation. The rebate agreement that you saw, Commissioner Concannon sent to Eli Lilly, simply regulates the transaction and the money that is generated from the transaction is then distributed. This is not a state acting in a market place capacity of buying drugs.

Now, we think it could be argued that the state functions as a market participant in the Medicaid program.

We would submit to the Court that that is an entirely different market, different program. We would cite to the Court the Supreme Court case that stands for the proposition that a state may not leverage its power in one market to regulate another one.

THE COURT: What is the case, the Alaska case?

MR. RUGG: Yes sir.

MR. RUGG: With regard to antiprofiteering, clearly today, or maybe speaking more precisely, November 2nd, the companies are at risk to be prosecuted. And the prosecution, it sounds like, would be founded upon their failure to submit to the regulation of the out—of—state transactions in the form of entering into rebate agreements. It's a real risk and the issue is precisely the issue we discussed earlier, the extraterritoriality element.

The failure to submit to the regulation of these foreign transaction exposes companies to that risk.

THE COURT: If it is extraterritoriality, again this is with respect to your argument of what you call the vast majority of the cases but not cases of a distributor in Maine?

MR. RUGG: Right.

THE COURT: Go ahead.

MR. RUGG: The statute makes findings. The state, the legislature has already determined that the manufacturers are in violation of this statute by making statutory findings that the companies charge excessive prices and realize excessive profits. So we have a statute that has made the finding.

We have a statute that imposes a standard of what is profiteering, and we have a statute that provides for immediate power to enforce it through prosecution. Additionally, we are at risk under the Unfair Trade Practices portion of the statute to private litigation over this issue.

Your Honor, I believe I have addressed the likelihood of success on the merits of the constitutional arguments. I would submit to the Court, as I indicated to you two days ago over the telephone, these issues can be decided legally. The facts are not in dispute. The extraterritoriality transactions, the rebate agreement that is indexed to Medicaid, the linkage to the other state transactions, the fact that the companies are compelled to enter into those agreements is not reasonably in dispute. So we submit to the Court that these issues are ripe for decision.

I have already addressed the hardship on the companies that would require the issuance of immediate injunction.

I would like to address the state's interest in avoiding an injunction today.

If you will, the status quo stands to be altered by the effectiveness and the implementation of the statute. There has never been prior authorization of Medicaid drugs for

other state purposes. There has never been the regulation of out—of—state transactions.

There has never been the overt public threat by a public official to run newspaper ads damaging these companies. None of that has occurred historically, it is prospective. The status quo will be preserved by this Court staying the implementation of this statute while the Court has the opportunity to decide these important constitutional issues.

The state cannot in good conscience be heard to argue that it has an interest in the enforcement of a non-constitutional statute.

And I would submit to the Court that we have not heard that from opposing counsel. We don't expect Mr. Hagler will argue to the Court this state has an interest in enforcing an unconstitutional argument. We think he will say the statute is constitutional.

So the real issue here is who will prevail at the end of the day on these critical constitutional issues on whether this statute is constitutional. We submit to the Court that the prudent course is to stay implementation and allow the judicial process to work.

Finally, with regard to the last prong, PUBLIC INTEREST, I don't think I need to belabor that because once again the public in Maine has an interest in its statutes complying with the federal constitution.

We all share that common interest, and that is the compeling public interest.

Your Honor, I would be happy to respond to any other questions the Court might have.

THE COURT: You have not addressed orally one argument that you addressed in writing concerning a third part of the statute which you characterized in writing as RETALIATION.

MR. RUGG: Yes, thank you, your Honor.

The statute, I would respectfully submit, is somewhat vague but we read that provision as saying the companies are compelled to do business in Maine. That if they are doing business in Maine, and because of the threat of this statute, they decided to reorder their business affairs to avoid the regulatory force of this statute, we believe they are at risk under the anti-retaliation provision of this statute. And if that's the case, we submit that it is unconstitutional for a state to enact a statute that compels companies based in Indianapolis Indiana to do business in Maine and to not leave Maine.

THE COURT: But at the moment that is a fairly abstract proposition, is it not, in the sense that I don't know what actions your companies might take to try to avoid Maine legislation. It is conceivable, is it not, that some of their activities might be subject to the statute and others might not? Isn't this a classic case of unripeness for a decision?

MR. RUGG: I understand the Court's concern but it seems that the Court could certainly render a limiting interpretation of the statute such as the Seventh Circuit in the K-S Pharmacy case.

One possible response is for the state to say, of course we don't construe this statute as mandating the continued presence of business operations in Maine. Of course we don't do that because that would be unconstitutional.

If the state does not take that position, we submit to the Court that it would be appropriate and right for the Court to render that type of decision.

Now, there may be further litigation in specific cases down the road that might move that line to apply to other transactions. But at this point we are simply talking about the fairly clear risk of, if a company responds to that statute and

changes its business transactions into another state, is it at risk?

THE COURT: All right, fine, let me find the think I have it.

MR. RUGG: The statutory provision, your Honor?

THE COURT: Yes, the language that refers to manufacturer or distributor or labeler that intentionally prevents limits or lessens or restricts the sale or distribution of prescription drugs in the state. Is that the one?

MR. RUGG: That's the one, your Honor.

THE COURT: All right, thank you, Mr. Rugg, I understand your argument.

MR. RUGG: Thank you very much, your Honor.

THE COURT: Mr. Hagler?

MR. HAGLER: Thank you, your Honor. It is both my duty and honor to argue in favor of this statute and that it is indeed constitutional.

The status quo, and that is what we are here today to decide, is whether the status quo should remain in pending litigation of the constitutionality of the statute, is not good enough. The status quo means that people will remain sick, and will remain unable to afford prescription drugs which they need.

The first test to determine is whether a Preliminary Injunction ought to issue ought to be a balance of the relative harms between the parties. And the state submits that requiring citizens to endure unaffordable drug prices, which is what the result of an injunction preventing implementation of this statute would be, outweighs the harms that are speculated to be the result of the statute by the plaintiffs.

We have cited studies in our papers, your Honor, which indicate that the price of 50 drugs most frequently used by the

elderly increased 4 times the rate of inflation in 1998, that the average price in Maine, the average retail price at the pharmacy for cash transactions in Maine of the 10 most prescribed drugs for the elderly were 86 percent higher at the pharmacy than the price for those same drugs that is charged to the federal government and to the drug companies' most favorite customers in Maine.

When one looks at the five most prescribed for the elderly, that is as high on average as 134 percent.

In the litigation of this case, the state will show that people are choosing not to fill prescriptions that their doctors write because they simply can't afford the price, that people are skipping dosage or splitting pills in a dangerous attempt to economize because they simply cannot afford the price. The public interest which provided the impetus for adopting this statute greatly outweighs the speculative effect on Interstate Commerce that the plaintiffs allege. For that reason we believe that the balance of harms way is in favor of denying the motion for injunction and also that because the state's interest so vastly weighs any speculative purpose on the part of the plaintiff, that the scrutiny on the issue of the likelihood of success on the merits of the case should be applied so that the plaintiffs are forced to prove a strong likelihood of success on the merits of the case. And we submit that this they have not done.

I was intending to address the Commerce Clause argument first, your Honor, but I would like, however, to take up the preemption argument because I think that I can illuminate some of the discussion regarding proposed rules by HCFA, the federal agency which regulates the federal aspects of Medicaid, and the use of a prior authorization in the Maine Rx statute as a mechanism for encouraging participation in that program by applying prior authorizations in the Medicaid program.

And I believe that I have a copy of the appropriate Federal Register and I would be happy with counsel's permission, and the Court's permission, to pass that up and to counsel.

THE COURT: Well you can do that. If you show it to him and he agrees that's fine.

MR. RUGG: Your Honor, may I have just a moment?

THE COURT: Of course.

MR. RUGG: Thank you, your Honor.

MR. RUGG: No objection.

THE COURT: Thank you.

THE COURT: Just so the record is clear, Mr. Hagler has handed me a portion of the Federal Register dated September 19, 1995, concerning proposed rules 42 CSR, 441 and 447. Go ahead.

MR. HAGLER: The federal Medicaid statute is vastly complicated, and as one can see by the number of pages that I have handed up to your Honor, some are proposed rules and comments and answers to comments which surround them. It is my understanding these rules have not been adopted. I will be referring to comments further along in my argument. It is important to recognize that the implementation of a prior authorization requirement in the Medicaid program for any particular drug is not a fait accompli as a result of the adoption of the Maine Rx program.

First, Medicaid establishes the right of the states to use prior authorizations in the Medicaid program. And what a prior authorization requirement is, with respect to a drug, is that a state is free to determine for any particular drug, that that drug should appear on what is called a prior authorization list. And what that means is that if a patient, entitled to receive Medicaid benefits, goes to their doctor, their doctor wishes to prescribe a particular drug, and if that drug appears on the list, then before Medicaid will reimburse the pharmacy

for filling that prescription, the doctor must speak with the state, and the doctor must speak with the state and have access to medical personnel to make the doctor's case that that drug is appropriate for that patient, that is appropriate for that patient because it won't counter act with another substance, another drug the patient might be taking. That it's the appropriate drug because there are no other alternatives which could help the patient with respect to the condition that they suffer, and perhaps even to explain to the state that other drugs were utilized to no effect and; therefore, this is the drug of last resort.

Medicaid requires that if a drug is placed on a prior authorization list, that there be a mechanism so that patients will be assured of getting that drug if they need it.

The Medicaid statutes can also be read such that the decision to place a particular drug on the prior authorization list, and the decision whether to prescribe it, must be governed by notions of medical necessity. But all that the Medicaid statute says about prior authorizations is that states may adopt that requirement in their Medicaid program. And then it says only two other things:

It says if you do have a prior authorization mechanism, there must be a provision for the phone to be answered when the doctor calls within 24 hours.

And there must also be a provision for dispensing on an emergency basis a 3 day suppliable drug which I believe is to cover instances in which the phone is not answered because of a holiday, and that is all the Medicaid statute speaks to.

Congress, therefore, has not affirmatively preempted in expressed language, the use of prior authorizations at all of events with respect to these two provisions. And, in fact, affirmatively granted to 'the states the right to engage in prior authorization.

Now, I would refer the Court and counsel to page 48473.

THE COURT: Go ahead.

MR. HAGLER: Of the federal register that I handed to the Court. And that is the area of the federal Register in which HCFA, the federal agency, is responding to concerns or questions that were received after proposing the rules. And I'm looking at the last column, the third column on the right, and towards the top of that column, the commentator is concerned about 3 things:

One is what if a state were to put on the prior authorization list all drugs of a particular manufacturer, or all drugs of all manufacturers, except the least expensive product in a therapeutic class.

Or—

And I'll skip to the third question. What if a state were to automatically place a prior authorization on the most expensive drug in a therapeutic class without regard to improved outcomes or reduction in total treatment cost associated with that more expensive drug therapy. And the answer of HCFA in construing Medicaid statute is clear, it is found further on down.

HCFA states: We believe that the state should be able to consider both clinical and economic criteria in their prior authorization programs as long as medically necessary drugs are not denied.

That would be okay.

The third question posed in the comments was:

It reads, the drugs if prior authorization—strike that, I'm not going to quote it. It asks—what if states try to get a better Medicaid rebate than the federal Medicaid rebate and used prior authorization, the threat of prior authorization of placing drugs on a prior authorization list, as the incentive to force drug companies to give that better Medicaid rate.

This appears to contemplate that it is possible for states to negotiate better Medicaid rebate for their Medicaid rebate than what the federal government negotiates for them and which otherwise applies across all the states.

This question suggests: What if a state were to say, and if you don't give us a better Medicaid rebate, we are going to consider using prior authorization.

And, again, HCFA says there is no problem with that.

They suggest that states can negotiate separate agreements for additional rebates as long as they comply with the requirements of the statute, and as long as the plan to consider prior authorization insures that patients will receive medically necessary drugs.

The states rules as proposed rules, and they have been proposed and published, as I understand, and we presented them in final form to the Court yesterday. And indeed they do differ in language, in slight variations in language from the form that they took at the time we wrote our briefs but the substance is the same. If a non-participating company, a company that refuses to enter into a Maine Rx rebate program, if they refuse to sign a rebate agreement and refuse to negotiate with the commissioner, the state's D U R committee (Drug Utilization Review Committee) can take off on a drug by drug basis, a decision tree of whether on a drug by drug basis, the drugs of those non-participating companies ought to be placed on that priorauthorization list.

THE COURT: Let me stop for a moment and have you elaborate on a couple of subjects. First of all help me with the Chevron analysis and what you have pointed me to in the Federal Register. You told me, I think, and Mr. Rugg told me of these proposed federal regulations have not been adopted. If that is so, do I have anything here that is authoritative in the Chevron sense on the Supremacy argument, and also can you tell me, do you know anything about why they have not been adopted, and what the status is?

My second question is going to be with respect to state regulations, let's leave it federal at the moment. Can you elaborate on that?

MR. HAGLER: I don't know the reason. I do not believe they were adopted because plaintiff's counsel cited to these in their papers as proposed, and I assume that is correct. And, again, of course these are statements of HCFA interpreting Congress' intent.

THE COURT: My question to you is: When they are still proposed and we have a response to comments but HCFA has not gone forward and adopted, do I have authoritative statements for Chevron purpose?

MR. HAGGLER: I don't know, your Honor, but I would be happy to brief that. I don't know the answer to that.

THE COURT: Let me turn you to the state regulation, your opponent's argument, I think I heard him say on the telephone, perhaps written papers, that the secretary can't rewrite the statute and that that is what he believes is happening here. Would you address that and explain to me what you mean by their decision tree approach as to whether or not an operating manufacturer will have its drugs automatically listed or not listed?

MR. HAGLER: Yes your Honor. First of all the statute states that the department shall adopt prior authorizations, as permitted by law, for companies that don't participate in the Maine Rx program. As permitted by law is the critical phrase and it's the phrase I believe the plaintiff's argument leaves out of the statute.

The commissioner and the department recognize that there is a constraint and it's expressed in HCFA's comments in the Federal Register to implementation of a prior approval, prior authorization process, and that constraint, aside from two examples that Congress put into the statute, is that in all event, or in any event patients entitled to Medicaid

reimbursement must receive drugs which are medically necessary. And the medically necessary determination comes about in two places, it comes about when the doctor calls the pharmacist or the pharmacist working for the state to request prior authorization. And there is always access ultimately to a physician who is employed by the State of Maine, who will make the medical necessity determination.

But it is also, as written in the rules, a guiding principle which the department will endeavor, has expressed an indication and will endeavor to consider, and to consider as the paramount factor in whether on a case by case basis any drug ought to be prior authorized.

THE COURT: Explain that to me. Suppose the XYZ pharmaceutical corporation manufacturer in New Jersey refuses to comply at all with the Maine Rx program and deadlines passes, are all its drugs then listed for prior authorization or are you telling me that there is then a further decision drug by drug of that company as to whether they will be listed or not?

MR. HAGLER: It is the latter.

THE COURT: So conceivably XYZ pharmaceutical of New Jersey, if they completely refuse to cooperate, that the state might conclude all of its drugs are so important that they are not on the prior authorizational list?

MR. HAGLER: That's correct, the hypothetical drug company could have a cure for aids and a cure for cancer that no other drug company has, and to place those drugs on the prior authorization list, because that company did not participate in the Maine Rx program, would have the result, would not be a decision consistent with medical necessity because any time a doctor wanted to prescribe that drug for cancer or HIV, the decision would be yes.

Now, I believe that the rules which affect this, I believe, are found in the pharmacy rules in section 80.05-3.

THE COURT: Say that again?

MR. HAGLER: The easier way, it's the thicker of the green packages and it's on page 8 with the numbers on the bottom, and then it's the second full paragraph on that page.

It reads: Drug Utilization Review.

THE COURT: Yes, I have it.

MR. HAGLER: It says: "The drugs of manufacturers that don't participate in the agreement shall be reviewed by the department as to the clinical appropriateness of prior authorization for those drugs under the Medicaid program.

Well, that implies that if you're going to make a clinical determination you have to do it on a drug by drug basis. Even further, the rule reads:

"Recommendations to prior authorize any of those drugs shall be referred to the Medicaid Drug Utilization Review Committee for a final determination of whether those drugs should be prior authorized in accordance with federal and state law. In all instances Medicaid recipients shall be assured access to medically necessary outpatient drug".

There's a similar provision in the Maine Rx rules regarding prior authorization. They are similar because they relate to each other.

THE COURT: I think you mentioned this to me on the telephone but tell me again. What is the ordinary amount of time under state necessary procedure law for public comment and—

MR. HAGLER: Ultimately I believe 40 days, 10 plus 30, and I believe, and I will correct myself after this hearing if I'm wrong but I believe the rules were published yesterday, meaning that notice went out in the paper yesterday and they were being sent to people who had requested them, and I have not calculated what the—

THE COURT: Let me take it one further step. If a broader reading of the statute were too broad and that this interpretation were necessary to preserve the statute on the face of the supremacy challenge, what do I do with the fact that these are still only proposed?

MR. HAGLER: The department didn't believe, and I hope I'm answering your question not with rhetoric, but the department didn't believe that "as permitted by law" in this area, as much as it is interfacing with Medicaid, could mean anything but a requirement that the decision to put a drug on a prior authorization list in Medicaid could be divorced of medical necessity. And so, notwithstanding that the rules are not adopted, I think that the rules in this respect or at least the spirit of these particular provisions is necessary.

THE COURT: I understand, thank you.

MR. HAGLER: Unless your Honor has anymore questions with respect to the preemption argument, turning back for a moment with respect to the Federal Register, the commentary, and this may go to the question that I was unable to answer. The commentary suggests that prior to the enactment of—no, strike that, I can't.

Turning to the Commerce Clause, and again it's important to recognize that in light of the strong state interest in adopting the statute, and the speculative nature of the harms alleged by the plaintiffs, they ought to have to prove that they are going to win almost to a high degree of certainty, likelihood should be in capitals and bold. But nonetheless we believe they have failed under the Commerce Clause argument.

First of all the rebate provision is designed to ensure lower prices for patients in Maine, it is directed towards obtaining lower prices in Maine for drugs and the Supreme Court in the *Brown-Forman* case stated, a state can seek lower prices for its citizens so long as it does not insist that producers or

consumers in other states surrender their relative competitive advantage.

Maine is not asking a consumer or producer in any other state to surrender any advantage that it might have.

Manufacturers are free to negotiate whatever price they want with respect to drugs sold in other states, and the consumers in other states are free and unrestrained by Maine statute to negotiate the best deal that they can. The statute does not co-op advantages enjoyed by those in other states. And for that reason, and for the reason that we have included in our papers, the Seventh Circuit decision in *K-S Pharmacies*, there is no objectionable Interstate Commerce of Maine's rebate program.

THE COURT: I understand your argument that there is no competitive disadvantage but the plaintiff has made two other arguments.

One, the extraterritoriality and the other is benchmark. Hasn't Maine gone outside its borders to control the transaction between the manufacturer and distributor in Kentucky or in Connecticut?

MR. HAGLER: By adopting a federal benchmark?

THE COURT: By providing that when the drugs ultimately end up in Maine that out-of-state manufacturer has to cough up some money to the State of Maine?

MR. HAGLER: The State of Maine is not regulating any transaction.

THE COURT: This is the market participant?

MR. HAGLER: No, your Honor, I make it in both areas. The State of Maine is not regulating any transaction outside of the State of Maine and it is not benchmarking its price to the price that pertains in any other state.

THE COURT: Let's put benchmarking aside for the moment. If XYZ Pharmaceutical company of New Jersey

sells to ABC distributor in Connecticut for $100 and then that drug ends up in Maine to be bought by a Maine consumer, doesn't Maine contemplate that the manufacturer has got to turn over some of that $100 to the State of Maine?

MR. HAGLER: Absolutely not.

THE COURT: And it has not gone outside its borders to regulate? The transaction for which that manufacturer thought it was getting $100 for the sale of that drug turns out to be $50.

MR. HAGLER: No. It has gotten $100 but it has elected to pay a rebate.

THE COURT: You used the word elected, is that important?

MR. HAGLER: If it enters into a rebate agreement, it's required to make the payment. The transaction between the manufacturer and it's out of state distributor remains the same. The plaintiff argues that this is the same as reducing or directly interfering or rewriting the contract which is out-of-state between the wholesaler and the manufacturer. But in *K-S Pharmacy* the Seventh Circuit said that an upstream effect on a wholesale manufacturer impose a have the do under transaction which happens to occur outside of the state which has the statute, does not implicate the Commerce Clause in a way which even requires balancing under the Pipe test.

THE COURT: How is this any different than it may duty on all drugs coming in the State of Maine and proceeds go to the Rx, which I take it Maine cannot the state commerce?

MR. HAGLER: You ask me an interesting question that I don't have a ready answer for it. I don't know that the state could be enjoined from a tax on a motion for Preliminary Injunction.

THE COURT: That may well be under the tax injunction provision. But I'm asking in a constitutional sense.

MR. HAGLER: And I think that if there is no difference, what the Court needs to consider is what the purpose is of what has been labeled as the Dormant Commerce Clause. And the purpose of the Dormant Commerce Clause, as the Supreme Court has articulated that in a variety of cases, is that the state cannot co-op for its self advantages which are in other markets, and Maine has not done that.

THE COURT: Your argument, if I understand from your papers and what you are saying now, the purpose of the Commerce Clause restrictions are to avoid discrimination and there is nothing discriminatory about Maine's statute; is that correct?

MR. HAGGLER: That's correct. And also that the State of Maine is not trying to obtain advantages like in the *Healy* and *Brown-Forman* that inure in other markets for itself. That is slightly different than discriminating from out-of-state and in state transactions. That is not allowing there to be a market occurring in different states throughout the nation that work according to their own competitive advantages. And Maine is not doing that, there is nothing about the rebate which injects Maine into the state of Vermont, or Massachusetts, or New Hampshire.

THE COURT: The other arguments Mr. Rugg has made is the benchmark argument, would you like to address that?

MR. HAGLER: Yes, thank you your Honor. Maine statute does not tie the rebate it seeks to obtain or the rebate it must obtain to the federal rebate. In other words, Commissioner Concannon is authorized by the statute to negotiate with drug companies for a rebate. And the statute does indeed suggest to the commissioner that he should use his best efforts to negotiate a rebate with drug companies that is better than or as good as the rebate which the state gets for those same drugs in the Medicaid program. But we are not tieing the rebate that the Commissioner must receive to that amount.

Now, of course the Commissioner began the negotiations, actually he began negotiations one step in the court of the drug companies because he did not ask for a rebate better than a Medicaid rebate. He submitted a proposal requesting a rebate in the Maine Rx or equal to the federal Medicaid rebate. The statute allows him of course to seek better, but the statute also permits the results that the rebate negotiated between the state and a particular drug company not be the federal benchmark. So, it is not correct to state that Maine is tieing its price or it's rebate in the Maine Rx program to the federal rebate. It is certainly looking to it, but even if it were so that the state were tieing it's rebate to the federal benchmark, again that is not a price that exists, the test of a price, that is not an attempt to obtain for Maine a price that another state was able to negotiate. There is no case of which I'm aware of that says using or even tieing a rebate to a federal benchmark is unconstitutional under the *Healy* and *Brown-Forman* cases. Those cases involve tieing prices in the regulating state with those of a particular state, or with those of the lowest of three bordering states but not an average. And I would submit that the use of an average does not enter in a Commerce Clause.

I will now turn to the market participation argument, your Honor.

Again, plaintiff must show a strong likelihood of succeeding on the merits. There is a complete defense, if you will, that the state has pled and argued in its papers and that is called the market participation exception. And the doctrine that has been developed by the Supreme Court has been that where a state acts as a market participant, actions which might in some fashion interfere with Interstate Commerce or interact or burden the state Interstate Commerce do not, because the state is not regulated, in fact act as market participant. There are two cases which we have pointed your Honor to, *Hughes versus Alexandria Scrap* case and *White versus Massachusetts*, and they are analogous to what Maine

is doing in that, and because in all instances the state is a purchaser.

And in Maine, here Maine purchases a very large quantity of drugs, 100 million dollars of drugs in the Medicaid program. I believe last week I was told the amount of the drugs purchased in the Medicaid program last week were 4 million dollars, just for the week. And last year at the same time the average was about 3 million dollars I believe. So it is an increasing amount and Maine is an important participant in that market, and it is using its market power to attempt to leverage it to obtain lower prices for other constituents in the state.

THE COURT: That's what Mr. Rugg says has gone too far. There is no question Maine is using its market power, given the large scale purchases you have described. And the cases you refer to, for example the White case in Boston who limited its construction projects to firms that employed 90 percent Boston residents, I think. And in the Hughes case, Maryland made it easier for in state owners to sell junk cars—

Mr. Rugg is saying what Maine is doing here, it is trying to use its leverage to effect something else, namely these uninsured-- how do you respond to that?

MR. HAGLER: The *White* case is most instructive because a narrow view—well, Mr. Ruggs says they're not in that market. In White the state of Massachusetts or the city of Boston was in the purchase of construction, they were hiring construction companies. One could argue that they are not in the market of hiring employees, they are in the market of hiring companies to go and build a public works program. But there is a separate market which the City of Boston does not have privity, if you will, in a contract sense, it is not in the market for construction for the employees that those construction companies hire, yet it was able to dictate beyond the purchase of construction contracts where the employees resided and the make up of the work force.

And we would argue the market that Maine is engaged in is the purchase of drugs and it's attempting to use its force to purchase drugs to lower prices for other people whom are in a sense a very closely related to the State of Maine, citizens who don't have drug insurance. And in a sense those other people are potential recipients of Medicaid dollars because if they go to the doctors and they can't afford to purchase the drugs, if they split prescriptions because of the high price, they can't afford them, it's possible they get sicker and are not able to work and find themselves in a situation of becoming eligible to receive Medicaid.

THE COURT: How do you distinguish the Supreme Court decision in the Alaska case?

MR. HAGLER: I argue it is hard to make an analogy to that case because Alaska was selling raw materials and in effect it was saying, further on you can't do something with that raw material, process that raw material in some other state, so vis-a-vis those other processors, and processors in other states, you are discriminating against these states and interstate commerce, that would be another way to distinguish that case.

And finally, your Honor, there's the Pipe balancing test and it is the State's position, and I want to make sure it is clear, that the Court need not get to the Pipe balancing test in order to rule for the state.

As I have argued earlier, we believe that there is no affect on Interstate Commerce, no affect on the rebate program that implicates interstate Commerce laws. But even though there is, again the state's interest vastly exceeds any effect on Interstate Commerce. Again, people are getting sick or getting sicker because they cannot afford their prescription drugs and we believe that when the balance is presented to the Court with facts in this case, that the interest of the state in passing this statute, the interest of its consumers of prescription drugs will so outweigh whatever minimal effect

plaintiff might prove on interstate commerce, and indeed plaintiff's claim that it has an affect on Interstate Commerce, that this statute has an affect on wholesale transaction is unquantified. There is nothing in the record which establishes a link to the size of the harm on Interstate Commerce that plaintiffs don't even flush out in their papers of facts. For that reason I believe that we will ultimately prevail on the Pipe test if the Court gets to that test.

For all of the foregoing reasons, unless your Honor has questions, the injunction ought to be denied.

THE COURT: I have a few questions. First of all does the LCD program have any bearing or does it simply happen to be in the statute, 'low cost for the elderly.

MR. HAGLER: It's another statute like the Maine Rx statute and also like Medicaid which uses the rebate mechanism.

The difference between the drugs for the elderly statute and the Maine Rx statute is that in the drugs for the elderly statute the State of Maine pays a portion, I don't believe all, a portion of the cost of the drugs. And I also believe without federal participation but I might be wrong on that.

THE COURT: It subsidizes?

MR. HAGLER: It's a subsidy, correct.

THE COURT: My second question is as to the anti-profiteering prohibition. You have argued that the rebate program is not extraterritoriality legislation because ultimately the consumer in Maine is ineffective—but if in fact the plaintiffs are correct that the vast majority of the manufacturer's sales distributors are outside the State of Maine, can Maine put a prohibition on the prices that they charge in New Jersey, Connecticut or elsewhere?

MR. HAGLER: I don't know that the statute prohibits—but it's possible. I take what your Honor is getting at is that

we could bring an action against the drug companies for prices which pertain in New Jersey or in some other state. I don't believe that the statute would be so utilized.

THE COURT: Then how would it be utilized? What do you understand to be the significance of that provision?

MR. HAGLER: The problem is, there has not been an investigation as contemplated by the statute. There hasn't been affirmative steps of which I'm aware to institute an action under that statute to flush out the facts. It is difficult enough to deal with the facts on the Preliminary Injunction with respect to the legality of the rebate provision than to contemplate what might occur, and what the facts might be in an action under that provision.

THE COURT: Mr. Rugg tells me the commissioner has alluded to that provision in his negotiating strategy.

MR. HAGLER: I would urge your Honor to read the letter that the commissioner has sent.

THE COURT: I will.

MR. HAGLER: I know how the manufacturer characterized it and how the state would respectfully characterize it as a little bit informative and a little bit bargaining but I don't think it's a threat.

THE COURT: Thank you very much. Mr. Rugg, rebuttal?

MR. RUGG: Yes, your Honor, I'd be happy to start with the LCD program. May I have just a moment?

THE COURT: Yes.

MR. RUGG: Your Honor, the statute makes it mandatory now if you look at the provision of the statute that defines rebate agreement, that is 2681 paragraph 3, it triggers the requirement to participate in a rebate program. I'm not sure that I am precisely answering the Court's question but our argument is that this, it intercepts with the rebate provision of

the statute which is subject to all the constitutional challenges we have been discussing.

THE COURT: I have two questions.

MR. RUGG: Yes sir.

THE COURT: Are you challenging anything concerning the LCD program or can I ignore it or is it not before me?

MR. RUGG: I believe it is not before you.

I have heard an awful lot of lawyers say they only have two questions, at least now I've heard judges can limit themselves to that limitation.

THE COURT: Sometimes.

MR. RUGG: Your Honor, with respect to Mr. Hagler's argument, it started and ended with the issue of how serious the harm is here to the citizens of this state. Drug prices are a serious issue. They are a serious issue that is addressed in all public forms presently, from presidential debates to state houses. We acknowledge the importance of this. It is a national issue. But the remedy that this state has selected, that is most poignantly described by Senator Pingree, is unconstitutional because this state says we can save the misery that our residents are suffering by violating the Constitution of the United States.

I respectfully submit to the Court it is not a proper issue in this case to weigh the hardship of uninsured residents struggling to acquire necessary medications, to weigh that against the constitutional imperatives here.

I would like to address the prior authorization.

We believe, and if the Court would like us to brief this, we would be happy to do so.

We believe that the draft HCFA regulations are informative but are not authoritative, not having been for purposes of a Chevron analysis.

We believe the Court does not have authoritative regulations before it.

What the Court does have is commentary that the state relies on.

You will recall Mr. Hagler saying, characterizing the commentary as what ifs, and responses. Well there are two conclusions.

One is: Clinical decisions should drive prior authorization.

And the second is if we depart from clinical to consider economic, economic is proper within the contents of the Medicaid statute. This state has an interest under the Medicaid statute of maximizing value for medicaid recipients in this state and that is the beginning and the end of that commentary.

We do not contend that the state is going to make prior authorization decisions under the Maine program that will deprive patients of the one drug that they have to have. Mr. Hagler talked about the aids patient or the cancer patient. How about the dozens of antibiotics that are in the market place that prior to enactment of the statute were not subject to prior authorization? But suddenly, with this statute, they are subject to prior authorization for only one reason: To compel participation in the program. And that, your Honor, has nothing to do with the federal program. That is the nub of our argument.

We concede the statute does not say no state shall use prior authorization as a gun to force people to participate in unrelated local programs but it should be self evident.

Your Honor, unless the Court has other questions of me, I thank you very much.

THE COURT: Thank you. Counsel, your arguments have been enormously helpful to me, they were both well prepared and you have presented the case well. Two or three questions

did come up during argument and if either of you want to elaborate briefly on them in the record, or add to your briefs filed originally, I would like to ask them to be filed by Monday. I know that does not give you much time but I know that you also want a decision from me quickly. If there are citations or that you feel you were not able to answer questions I had, then by a brief response I will accept that and I will use it.

Again, I thank you very much, the case has been thoroughly presented and as soon as I have whatever additional submissions, I will proceed to enter a decision as soon as possible. Thank you very much. The Court is in recess.

(Whereupon the Court recessed at 10:33 AM)

CERTIFICATE

I hereby certify the foregoing is a true and accurate transcript of my stenographic notes taken at the time and place herein set forth.

Dated at Portland, Maine this 19th day of October 2000.

/s/
Official Court Reporter

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October 23, 2000

Honorable D. Brock Hornby
Chief U.S. District Judge
United States District Court
156 Federal Street
Portland, ME 04101

Re: *Pharmaceutical Research and Manufacturers of America v. Kevin Concannon, et al.*
Docket No. 00-CV-157-B-H

Dear Judge Hornby:

This letter is submitted in response to your invitation to counsel for the parties, at the close of oral argument on Thursday, October 19, 2000, to address in writing certain issues that arose during that hearing. We appreciate this opportunity and hope that the following clarifications will be of assistance to the Court.

Proposed Regulations of HCFA and the Maine Department of Human Services

The Court raised questions during the hearing concerning the legal significance of (a) the federal Health Care Financing Administration's ("HCFA") proposed regulations implementing the Medicaid prescription drug benefit 60 Fed. Reg. 48,442 (Sept. 19, 1995), and (b) the Maine Department of Human Services' proposed regulations implementing prior authorization under the Maine Rx program, a copy of which was filed with the Court on October 19, 2000.

The Court inquired about the deference due, if any, to HCFA's proposed regulations under the rubric of *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Legal precedents confirm that proposed (rather than final) regulations and interpretive commentary are not owed *Chevron* deference. *See e.g., Tedori v. United States*, 211 F.3d 488, 492 & n.13 (9th Cir. 2000) (stating that "proposed regulations carry no more weight than a position advanced on brief") and cases cited therein; *Teweleit v. Hartford Life & Accident Ins. Co.*, 43 F.3d 1005 (5th Cir. 1995) (stating that a regulation never adopted "thus has no precedential authority"). Last term, the Supreme Court indicated that *Chevron* deference is reserved for administrative interpretations formally arrived at "after, for example, a formal adjudication or notice-and-comment rulemaking." *Christensen v. Harris County*, 120 S. Ct. 1655, 1662-63 (2000) (rejecting *Chevron* deference to an interpretation in an opinion letter). Accordingly, PhRMA respectfully suggests that proposed regulations warrant the Court's consideration only to the extent that they are persuasive, *Christensen*, 120 S. Ct. at 1663; no deference is required or appropriate.

It was for their persuasive force that PhRMA's Motion invited the Court's attention to HCFA's proposed regulations, and particularly to HCFA's goal of ensuring that any use of prior authorization has "medical necessity as its *primary* concern." PhRMA Motion at 17-18, discussing 60 Fed. Reg. at 48,454-55 (emphasis added). Maine's new use of prior authorization has the Maine Rx program's funding, not medical necessity for Medicaid patients, as its primary concern. PhRMA maintains that the inconsistency between HCFA's stated goal and that of the Maine Rx program is evidence of the latter's conflict with congressional objectives.

Even as persuasive authority, the HCFA proposed regulations cannot be stretched beyond their logical boundaries. At oral argument, the State referred the Court to

HCFA commentary suggesting that a state could take not only clinical but also economic considerations into account in imposing prior authorization. *See* 60 Fed. Reg. at 48473. HCFA's comments, however, are addressed to economic considerations germane to the Medicaid program, and only the Medicaid program. As HCFA recognized, it is certainly appropriate for state Medicaid authorities to consider economic criteria in prior authorization *for the benefit of the Medicaid program*. But HCFA never suggested that it would be appropriate to consider economic criteria *unrelated to Medicaid*—such as funding non-Medicaid programs like Maine Rx—in imposing prior authorization.

The Court also asked whether draft Maine Rx regulations on prior authorization could cure the statute's infirmities under the Supremacy Clause alleged by PhRMA. PhRMA contends that, whether proposed or final, the Department's regulations cannot save the Maine Rx prior authorization requirement from preemption. The State has not contested that prior authorization imposes a procedural burden on Medicaid doctors and patients, and consumes Medicaid resources (*e.g.* the time and resources of the Medicaid Drug Utilization Review Committee); in fact, the State outlined that burdensome process in some detail at oral argument, *see* Tr. 26-27. PhRMA maintains that the very imposition of that burden, for reasons unrelated to any Medicaid purpose, conflicts with the federal Medicaid program. Regardless of how State regulations implement Maine Rx prior authorization, that burden serves no Medicaid purpose and works to the detriment of the Medicaid program and its beneficiaries. PhRMA respectfully suggests that the State's regulations are of marginal relevance at best, not because they are merely proposed and not final, but because they do not cure the Maine Rx statute's preemption in any event.

Mandatory Participation in the Maine Rx Rebate Program

At oral argument, the State responded to a question from the Court regarding the alleged extraterritoriality of the Maine

Rx rebate program by suggesting that manufacturers would "elect" to pay the rebates. Any suggestion that the Maine Rx program is somehow voluntary simply misperceives the statute. The statute specifically mandates tat manufacturers "*shall* enter into [] rebate agreement[s]" (emphasis supplied) and sets out severe penalties (prior authorization, negative publicity, and profiteering prosecutions) for any manufacturer who does not comply with the statute. Further, the rebate program is not a "negotiation," as the State suggests; the statute does not give manufacturers the option of failing to reach an agreement. Manufacturers thus cannot "elect" not to pay Maine Rx rebates.

Situs of Prescription Drug Sales

Several colloquies with the Court centered on the significance of the situs of manufacturers' prescription drug sales. In connection with its extraterritoriality challenge, PhRMA maintains that sales taking place outside Maine cannot, consistent with the Commerce Clause, be subject to the Maine Rx rebate requirement.

The situs of sales, moreover, relates to the ripeness of PhRMA's challenge to the anti-retaliation provision of the statute: manufacturers are presently precluded from shifting those in-state sales that they do make (if any) to out-of-state distribution channels. The law's interference with the mobility of interstate commerce is especially immediate if the anti-retaliation provision prevents manufacturers from shifting the situs of their in-state sales (if any) to take advantage of a ruling from this Court that the Maine Rx rebate cannot be applied to out-of-state sales.

LCD Program

To clarify our response to a question from the Court regarding Maine's Elderly Low Cost Drug Program, PhRMA confirms that the LCD program is not at issue in its motion for a preliminary injunction, and thus is not before the Court at this time.

We thank the Court for the opportunity to appear before it last week, and for this opportunity to supplement and clarify the record.

Respectfully submitted,

/s/
Bruce C. Gerrity

BCG/rgy
cc: Andrew S. Hagler, Esq.

STATE OF MAINE
DEPARTMENT OF THE ATTORNEY GENERAL
6 STATE HOUSE STATION
AUGUSTA, MAINE 04333-0006

October 23, 2000

The Honorable D. Brock Hornby
Chief U.S. District Judge
156 Federal Street
Portland ME 04101

Re: *Pharmaceutical Research v. Concannon, et al.*
Case No.: 00-157-B

Dear Judge Hornby:

We appreciate the opportunity to submit additional briefing on issues raised by the Court but not fully addressed during the hearing of October 19, 2000.

At the hearing the Court asked what might be the effective date of the proposed rules implementing the Maine Rx program. The notice of rulemaking was filed with the Secretary of State on October 10, 2000. Pursuant to the Maine APA, a public announcement was posted in newspapers on October 18. A public hearing is scheduled for Wednesday November 8, 2000, and written comments from the public are due no later than November 20, 2000. The rules can become effective as soon as any responses to the comments and/or minor revisions to the proposed rules are completed, and the review of the Attorney General is obtained. While the ultimate effective date may be as long at 155 days from the public comment deadline, the Department intends to complete the rulemaking process no later than January 1, 2001 so that the rules are in effect when the Maine Rx Program begins.

The remainder of this letter addresses: 1) the application of *Chevron* principles to rules of a federal agency that have been

proposed but not adopted, and 2) whether the Maine Rx Program imposes a "duty."

1. *It Is Unnecessary To Accord Special Deference Under Chevron To The Proposed Rules Promulgated By The Federal Health Care Financing Administration.*

Both parties have called the Court's attention to proposed rules of the Health Care Financing Administration ("HCFA") entitled *Medicaid Program Payment for Covered Outpatient Drugs Under Drug Rebate Agreements with Manufacturers*, 60 Fed. Reg. 48,442 (Sept 19, 1995). In its initial brief, Plaintiff contended that HCFA proposed rules support its contention that the use of prior authorization in the fashion contemplated by the Maine Rx program would defeat Congress's intent to "assur[e] access by Medicaid beneficiaries to prescription drugs where medically necessary." *Plaintiff's Memorandum of Law* at 17.

During the hearing on October 19, defendants cited a different portion of the same proposed rules to demonstrate that HCFA's interpretation actually supports the State's position. First, according to HCFA, "[s]tates should be able to consider both clinical and economic criteria in their prior authorization programs as long as medically necessary drugs are not denied." 60 Fed. Reg. 48,442 at 48,447. Second, HCFA apparently agrees that a State can use its prior authorization power to attempt to negotiate for itself further financial benefits from drug manufacturers beyond those provided by the "national" Medicaid rebates negotiated by HCFA. *Id.*

Maine submits that HCFA agrees with the underlying premise of our preemption argument — that Congress did not intend to impose any requirement on the use of the prior authorization power it gave to the states other than the two, ministerial requirements specifically set forth in the statute. 42 U.S.C. 1396r-8(d)(5). To te extent that the requirement that Medicaid recipients receive "medically necessary" drugs

is viewed as a further restriction on the use of prior authorizations, the Maine Rx statute only authorizes imposition of prior authorization requirement "as permitted by law", and the Department's proposed rules ensure that all medically necessary drugs will be dispensed.

The State does not believe that Congress's intent with respect to prior authorizations is ambiguous. The proposed rules reflect this clarity but it is not necessary to resort to any statement by HCFA to discern Congressional intent. The State cited HCFA's proposed rules primarily to rebut Plaintiffs assertion that the proposed rules require a finding that Congress intended to greatly limit the use of prior authorizations. In short, the question of whether proposed rules, as opposed to *final* rules, are to be afforded deference pursuant to *Chevron U.S.A. Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984), need not be reached. However, if congressional intent were not manifest by the statute itself, HCFA's proposed rules are instructive for the proposition that Congress did not intend to limit use of prior authorizations other than in the limited fashion specifically set forth in the Medicaid statute.

2. *The Rebate Agreement Does Not Constitute A "Duty."*

At the October 19 hearing, the Court asked whether the Maine Rx Program rebates could be compared to an impermissible duty on the importation of drugs.

The Maine Rx Program rebate is not a duty, for several reasons. The rebates do not discriminate against out-of-state goods. The Commissioner is directed to negotiate rebate agreements with all drug manufacturers, irrespective of where the manufacture is located and where its drugs come to Maine from. The Act applies equally to out-of-state drug manufacturers and to any manufacturers which are located in Maine now or in the future. The purpose of the Maine Rx Program is not to discriminate among goods based upon their source. Rather, the rebates are intended to assist the State in

lowering the prices of drugs made by participating manufacturers.

Also, duties, like other taxes, generally apply at a uniform rate across all goods and all taxpayers. Here, however, the Act contemplates negotiation of the rebate by each participating manufacturer. Moreover, not all drugs of a participating manufacturer that enter into the State are subject to a rebate. Instead, only drugs which are ultimately purchased by an uninsured citizen at a pharmacy trigger a rebate payment.

Finally, governments generally enforce the obligation to pay a duty with either criminal or civil sanctions, or by prohibiting the entry of the good. Here, however, the only consequence of failing to negotiate a rebate agreement is the possibility that certain drugs of a manufacturer will be subject to prior authorization requirements before they are reimbursed through the Maine Medicaid program.

For these reasons, rebate payments made pursuant to agreements negotiated between the Commissioner and pharmaceutical manufacturing companies cannot be considered a "duty." As noted at the hearing, however, if the rebate agreement contemplated by the statute is somehow determined to be a form of taxation, the federal district courts lack jurisdiction to grant the requested injunction under the Tax Injunction Act, 28 U.S.C. § 1341.[1]

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[1] Even if the rebate agreements were considered a "tax," the Commerce Clause does not prohibit state taxes that have some extraterritorial reach. In *Complete Auto Transit, Inc. v. Brady*, 430 U.S. 274 (1977), the Supreme Court determined that a state tax will be sustained so long as it (1) is applied to an activity with a substantial nexus with the taxing state; (2) is fairly apportioned; (3) does not discriminate against interstate commerce; and (4) is fairly related to the benefits received by the taxpaying entity from access to the state. *See also Quill Corp. v. Heitkamp*, 504 U.S. 298 (1992). The *Complete Auto Transit* analysis would necessarily entail considerable factual inquiry in this case. For instance, even though Plaintiff has alleged that very few of its wholesale

Thank you for considering these additional comments.

Very truly yours,

/s/
Andrew S. Hagler
Assistant Attorney General

/s/
John Brautigam
Assitant Attorney General

transactions occur in Maine, it is likely that individual drug manufacturers engage in sufficient sales and promotion activity within the State to satisfy the "substantial nexus" prong of the *Complete Auto Transit* test.

UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH
AND MANUFACTURERS OF
AMERICA,

PLAINTIFF

v. Civil No. 00-157-B-H

COMMISSIONER, MAINE
DEPARTMENT OF HUMAN
SERVICES, ET AL.,

DEFENDANTS

ORDER ON MOTION TO INTERVENE

On October 26, 2000, I granted a preliminary injunction in favor of the plaintiff against specified parts of Maine's prescription drug pricing legislation. On November 9, 2000, the state defendants appealed. On November 13, 2000, certain would-be intervenors filed a motion to intervene under Fed. R. Civ. P. 24, along with a motion to alter or amend judgment and motion to dismiss Count V of the plaintiff's Complaint. They also requested that I grant them an extension of time, if they are allowed to intervene, to file their own notice of appeal from the preliminary injunction of October 26, 2000. These would-be intervenors have previously participated in the lawsuit by filing an *amicus* brief.

The law on this subject—private plaintiffs attempting to intervene in support of state legislation at the same time the Maine Attorney General is defending the legislation—is well established in this Circuit. *See Daggett v. Comm'n on Gov't Ethics & Election Practices*, 172 F.3d 104, 109-111 (lst Cir. 1999). For intervention as of right, I examine four factors: timeliness; interest in the property or transaction that is the

subject of the lawsuit; effect on ability to protect that interest; and adequacy of representation.

(1) The motion to intervene is timely as to any further proceedings in this trial court because at this point no scheduling order has been entered, no discovery has taken place and the lawsuit is only beginning. It is untimely, however, as to the preliminary injunction issues. Those issues were fully briefed and argued orally following conferences with the Court in preparation for those events. There was abundant opportunity for the intervenors to have moved earlier to intervene. The preliminary injunction has now issued and been appealed and a briefing schedule has been set for the appeal. There is no good excuse for the intervenors not to have moved to intervene earlier if preliminary injunction was their concern.

(2) The would-be intervenors have a distinct and real interest in the lawsuit. Specifically, they are two individuals who cannot otherwise afford needed prescription medication, a membership-based organization that advocates on behalf of Maine's seniors particularly with regard to affordable healthcare, and a family practice physician whose prescription practices are affected by the ability of his patients to pay for medication.

(3) Disposition of this lawsuit will undoubtedly affect dramatically the proposed intervenors' ability to protect their interests because the constitutionality of Maine's attempt to lower the prices for prescription drugs will be determined by the outcome.

(4) As in *Daggett*, the primary issue is adequacy of representation. 172 F.3d at 111 (noting that the "heart of the case" is whether the Attorney General adequately represented their interests). Here, as in *Daggett*, the Attorney General's Office is aggressively defending the statute. Unlike *Daggett*, this statute did not result from a citizen initiative, but is a statute actively supported by the Governor and the

Legislature. The would-be intervenors argue that because their health is at stake the normal presumption in favor of adequate representation by the Attorney General should be reduced. But I do not rely on presumption. The Attorney General is vigorously defending the case, far more than just "adequately." In addition, they point to two arguments they want to make that the Attorney General has not made. The first argument—that the plaintiff is not irreparably harmed—goes only to the preliminary injunction where, I have concluded, the motion to intervene is untimely. The second argument goes to the merits. The intervenors want to argue that the plaintiff has no standing to make its supremacy challenge based upon federal Medicaid law, an argument that the State did not make at the time of preliminary injunction arguments. As in *Daggett*, however, such tactical disagreements are not enough to require intervention as of right automatically. 172 F.3d 104, 112 (1st Cir. 1999). The refusal to present an obvious argument must be "extreme." *Id.* These would-be intervenors can present their argument fully and ably through "*amicus* plus" status, which I now grant them. Unlike factual development, it does not require intervenor status. Moreover, it may well be that the State will see fit to adopt the argument on the merits after the preliminary injunction stage. Lawyers must make tactical and strategic choices as to what arguments to press given the limits of time for oral arguments and page limits for briefs. The fact that a lawyer chooses not to make a particular argument at a given stage does not demonstrate inadequacy of representation. Instead, the record makes abundantly clear that the Attorney General is vigorously defending this legislation with the full support of state government.

Finally, permissive intervention serves no useful purpose here where *amicus* plus status is granted and the Attorney General is representing all the interests of the State in defending the legislation. I make the following Order as I did in *Daggett v. Webster*, 190 F.R.D. 12 (D. Me. 1998).

1. Notice and service of all documents and events shall be given to the would-be intervenors' counsel just as if they were parties in the case.

2. If there are witnesses at trial or deposition where the Attorney General's Office is willing to let the would-be intervenors' lawyer conduct the examination or cross-examination in place of an Assistant Attorney General, that is permitted. What is not permitted is examination or cross-examination by both.

3. I expect that, as appropriate, the Attorney General's Office will take full advantage of any offer of resources, evidence or assistance from the would-be intervenors where to do so will help the Attorney General defend the constitutionality of the statute.

4. Finally, the motion to intervene can be renewed if and when the would-be intervenors have evidence that the case is not being fully and properly presented by the Attorney General.

For these reasons, the motion to intervene is *DENIED* and the motion for extension of time to file a notice of appeal is *DENIED* because I have denied the motion to intervene. No action is necessary on the motion to alter or amend judgment and to dismiss Count V of the plaintiffs Complaint.

SO ORDERED.
DATED THIS *14th* OF DECEMBER, 2000.

/s/

D. Brock Hornby
United States District Judge

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SOCIAL SECURITY ACT § 1927
42 U.S.C. §§ 1396, 1396a(a)(10)(A)-(C), (a)(19),
(a)(30)(A)-(B) & (a)(54), 1396c, 1396d(a) & 1396r-8(g)

42 USCA § 1396: Appropriations

For the purpose of enabling each State, as far as practicable under the conditions in such State, to furnish (1) medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services, and (2) rehabilitation and other services to help such families and individuals attain or retain capability for independence or self- care, there is hereby authorized to be appropriated for each fiscal year a sum sufficient to carry out the purposes of this subchapter. The sums made available under this section shall be used for making payments to States which have submitted, and had approved by the Secretary, State plans for medical assistance.

42 USCA § 1396a: State plans for medical assistance

(a) Contents

A State plan for medical assistance must—

* * * *

(10) provide—

(A) for making medical assistance available, including at least the care and services listed in paragraphs (1) through (5), (17) and (21) of section 1396d(a) of this title, to—

(i) all individuals—

(I) who are receiving aid or assistance under any plan of the State approved under subchapter I, X, XIV, or XVI of this chapter, or part A or part E of subchapter IV of this chapter (including